

MEDICAL GROUP LABORATORIES

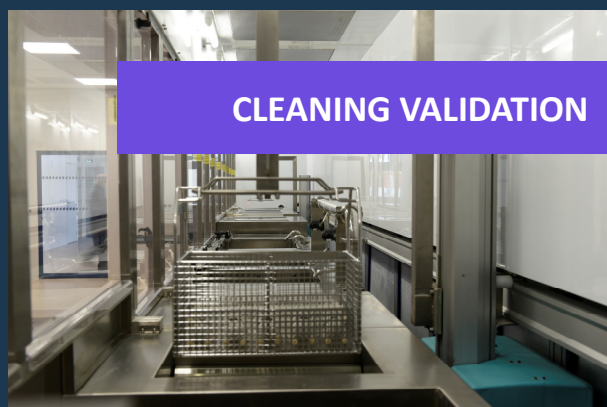
Expertise supporting compliance

Specialist in the coating and packaging of implantable medical devices, MedicalGroup has integrated laboratories allowing to conduct the main tests required for validation or monitoring of your routine productions.

The tests, carried out internally or in collaboration with partner laboratories, cover a wide range of services in **microbiology**, **cleaning** validation, **packaging** integrity, characterization of **powders and coatings** by plasma spraying.



MICROBIOLOGY



CLEANING VALIDATION



COATINGS CHARACTERIZATION



PACKAGING

The laboratories are accredited by **COFRAC (accreditation N°1-6644)**, according to ISO 17025 standard. Details of the accreditation scope are available on the website www.cofrac.fr

MICROBIOLOGY

MedicalGroup performs the microbiological tests required for the marketing and monitoring of your products.

- Bacterial endotoxins **European Pharmacopoeia 2.6.14**
USP<85> and <161> Method D
- Bioburden **NF EN ISO 11737-1**
- Sterility tests **NF EN ISO 11737-2 and Eur. Ph. 2.6.1**
USP<71>
- Initial and quarterly dose audits
- Microorganisms identification by MALDI TOF, PCR sequencing



Test method validation

In partnership with customers, our laboratory team prepares protocols and validation reports for analytical methods for bioburden, endotoxins and sterility tests.



PACKAGING

MedicalGroup has capabilities to carry out a complete assessment of packaging stability and integrity.

- Tensile strength test **NF EN 868-5 and ASTM F88/F88M**
- Visual inspection **ASTM F1886**
- Peel tests **NF EN 868-5**
- Leak detection **ASTM F1929 and ASTM F3039**
- Transit simulation **ASTM D4169 and ISTA**
- Accelerated aging **ASTM F1980**
- Microbial barrier **ASTM F1608**
- Bubble test **ASTM F2096**



CLEANING VALIDATION

MedicalGroup advises and guides you for your cleaning validations according to ISO 19227 standard.

- TOC residuals **NF EN 1484**
- THC residuals **NF EN ISO 9377-2**
- Inorganic residuals **ISO 10993-12**
- Cytotoxicity test **ISO 10993-5**
- Bioburden **NF EN ISO 11737-1**
- Bacterial Endotoxins **Eur. Ph. 2.6.14**
USP<85> and <161> Method D



In addition, depending on the device substrate: corrosion tests (**ASTM A967 Methods A and E**)

Specific protocols can be designed according to your needs and products.

COATINGS CHARACTERIZATION

Our laboratory is able to perform a complete assessment of the performance and properties of powders and plasma coatings, according to the requirements of ISO 13779, ISO 13179-1 and FDA guidances.



Chemical tests

- Phases, crystallinity and Ca:P ratio by XRD **ISO 13779-3**
- Heavy metals and trace elements on HA **ISO 13779-3**
- Chemical analysis on titanium **ISO 13179-1 and ASTM F1580**
- Corrosion **ASTM A967 Methods A and E**

Mechanical tests

- Tensile strength **ASTM F1147 and ISO 13779-4**
- Shear strength **ASTM F1044**
- Fatigue shear test **ASTM F1160**
- Abrasion (Taber) **ASTM F1978**
- Fatigue bending **ASTM F1160**

Morphology tests

- Thickness and porosity **ASTM F1854**
- Roughness Ra, Rt **NF S94-071**

Do not hesitate to ask us for other types of tests related to your products or projects.
We will study your request, internally or with partner laboratories.

Our laboratories are located in Saint-Priest, near Lyon in France, on a new site with large capacities and state of the art equipment.

We rely on trained and skilled people and expertise developed for more than 30 years.



33 route de Lyon - 69800 Saint-Priest - France

(+33) 4.72.81.22.62

www.medicalgroup.fr

Contact: info@medicalgroup.fr

